



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/614,653

07/07/2003

Andrew Kim

90448U

7515

20529

7590

03/13/2008

NATH & ASSOCIATES
112 South West Street
Alexandria, VA 22314

EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

03/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/614,653	Applicant(s) KIM, ANDREW	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on 15 October 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the trailing edge" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

Regarding Luscher, Applicant argues that Luscher does not disclose an assembly capable of drawing a suture into a barrel. This is not persuasive because the plunger can move in both directions and is therefore capable of drawing the suture into the tube.

Regarding Luscher in view of Sontag, Applicant argues that Sontag does not teach an opening with both a leading and trailing edge. This is not persuasive because Applicant is not claiming a leading edge.

Regarding Weng in view of Luscher, Applicant's argues that Weng in view of Luscher do not teach introducing the suture material from outside the apparatus. This is

not persuasive because the suture material was not formed inside the syringe and therefore had to be introduced into the syringe at some point before use.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by
Luscher (US Patent 6,299,590).**

Luscher'590 discloses a device containing a syringe (see Figure 5) containing a barrel (31) and a plunger (32) and a connector (35) capable of being detachably mounted to a needle (17). The barrel is sized and shaped for holding a suture and the fluid used for expelling the suture (column 1, line 45-57). Further, the device contains an elongated cannulated needle (17) (column 4, line 66-67) capable of receiving and releasing a suture (column 4, line 55-67). The distal end of the needle (4) can have a sharp distal point (see Figure 5) and is configured to receive a suture extending from the lumen of the needle.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luscher'590.

Claims 2-4: Luscher'590 does not disclose that the needle has a particular shape at the distal end. However, it is old and well known to modify the shape of needles to aid

in accessing a particular region of the body, especially if the region would be more easily accessed with a needle of a different shape.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5-7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luscher'590, as applied to Claim 1, in further view of Sontag (US Patent 5,236,443).

Luscher'590 teaches the limitations of Claim 5 except for a rounded tip of a suture needle.

Sontag'443 teaches a suturing with openings at the end that are slightly rounded to protect the surgeon from accidental cuts or punctures (column 4, lines 15-21). It

would have been obvious to one skilled in the art at the time the invention was made to use rounded needles in order to protect the user from accidental cuts.

Claims 6-7: Luscher'590 does not disclose that the needle has a particular shape at the distal end. However, it is old and well known to modify the shape of needles to aid in accessing a particular region of the body, especially if the region would be more easily accessed with a needle of a different shape.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luscher'590, as applied to Claim 1, in further view of Olovson (US Patent 6,702,786).

Luscher'590 teaches the limitations of Claim 8 except for a stiffening cover of the needle.

Olovson teaches a syringe with a stiffening cover (2) over a needle (14) in order to protect the needle. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Luscher'590 with a stiff cover, as taught by Olovson, in order to protect the needle.

Claims 1 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al. (US Patent 5,441,507) in view of Luscher'590.

Claims 1, 9, 11, 12, 14: Wilk'507 discloses a suturing instrument that contains an elongate tubular member (112), first and second jaws (114, 116) being movable relative to each other (column 12, lines 3-5) with a means for moving the jaws (144). The jaws contain an open end at the distal end of the tubular member (see Figure 5), and suture

distributor (140) that contains a needle (130) with a circular opening that extends through the tubular member and into the jaws (see Figure 5).

Wilk'507 does not disclose that the suture distributor is a syringe.

Luscher'590 discloses a device containing a syringe (see Figure 5) containing a barrel (31) and a plunger (32) and a connector (35) capable of being detachably mounted to a needle (17). The barrel is sized and shaped for holding a suture and the fluid used for expelling the suture (column 1, line 45-57). Further, the device contains an elongated cannulated needle (17) (column 4, line 66-67) capable of receiving and releasing a suture (column 4, line 55-67). The distal end of the needle (4) can have a sharp distal point (see Figure 5) and is configured to receive a suture extending from the lumen of the needle. It would have been obvious to combine the device taught by Wilk'507 with the syringe taught by Luscher'590 because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claim 10 and 13: Wilk'507 in view of Luscher'590 does not disclose that the needle has a particular shape at the distal end. However, it is old and well known to modify the shape of needles to aid in accessing a particular region of the body, especially if the region would be more easily accessed with a needle of a different shape.

Claims 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weng (US Patent 5,569,270) and Luscher'590.

Claim 15 and 18: Weng'270 teaches a method of suturing which includes providing an elongate needle (46) having a lumen extending from the proximal end to the distal end that is capable of passing a suture (column 2, lines 45-60). Suture material is introduced into the needle (column 2, lines 54-56 and column 3, lines 55-63). Liquid fills the syringe, the needle is passed through the tissue to be sutured and the suture is expelled with the force of the liquid flow (column 2, lines 45-60). Weng'270 discloses a stiffening cover (60) that covers most of the needle (see Figure 1). Weng'270 does not teach a syringe to expel the liquid.

Luscher'590 teaches a syringe for expelling the liquid and the suture because this device is well known for expelling fluid, contains space for holding a suture, and is easily controlled by the user. It would have been obvious to one skilled in the art at the time the invention was made to modify the fluid control device taught by Weng'590 with a syringe taught by Luscher'590 because syringes provide a simple means for expelling liquid that is very controllable by the user.

Claim 17: Weng'270 does not disclose that the needle has a particular shape at the distal end. However, it is old and well known to modify the shape of needles to aid in accessing a particular region of the body, especially if the region would be more easily accessed with a needle of a different shape.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weng'270 in view of Luscher'590.

Weng'270 in view of Luscher'590 teach the limitations of Claim 16, except for drawing the suture back into the needle with the syringe.

Since the suture is pushed out of the syringe, it would be obvious to try putting the syringe in with the same method. The claim would have been obvious because a person of ordinary skill has good reason to pursue the known options within his technical grasp. If this elads to the anticipated success, it is likely the product not of innovation, but of ordinary skill and common sense.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weng'270 in view of Luscher'590, as applied to Claim 15, and in further view of Wilk'507.

Claim 19 and 20: Weng'270 in view of Luscher'590 teaches the limitations of Claims 19 and 20 except for providing an elongate tubular member with jaws onto the suturing syringe.

Wilk'507 discloses a suturing instrument that contains an elongate tubular member (112), first and second jaws (114, 116) being movable relative to each other (column 12, lines 3-5) with a means for moving the jaws (144). The jaws contain an open end at the distal end of the tubular member (see Figure 5), and suture distributor (140) that contains a needle (130) with a circular opening that extends through the tubular member and into the jaws (see Figure 5). It would have been obvious to combine the device taught by Wilk'507 with the syringe taught by Weng'270 in view of Luscher'590 because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./
Examiner, Art Unit 3734

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773